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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,063	02/28/2002	Rocco Casagrande	11641/39	7445
23838	7590	09/17/2004		EXAMINER
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005				NAFF, DAVID M
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/084,063	CASAGRANDE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 February 2002.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-214 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-214 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date, _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

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***Election/Restrictions***

Claims in the application are 1-214.

Restriction to one of the following inventions is required under  
35 U.S.C. 121:

- 5       I.    Claims 1-37, 112-145 and 178 drawn to a device for arraying  
          cells comprising a substrate having magnetic receptacles  
          comprising highly-magnetically-permeable material and a  
          localized magnetic field gradient, an external magnetic  
          field and a cell delivery device, classified in class 435,  
10        subclass 289.1.
- II.    Claims 38-72 and 146-178, drawn to device for arraying cells  
          comprising a substrate having magnetic receptacles in a  
          discrete pattern and comprising a permanent magnet and a  
          localized magnetic field gradient, classified in class 435,  
15        subclass 283.1.
- III.   Claims 73-111, drawn to a method of arraying cells on a  
          substrate using a substrate having magnetic receptacles such  
          that each of the receptacles trap about 1-5 cells associated  
          with a magnetic material, classified in class 435, subclass  
20        173.1.
- IV.    Claims 179-196, drawn to a method for arraying about 1-5  
          cells on a discrete location for further experimentation by  
          associating cells with magnetic beads using a bioaffinity  
          ligand and delivering the associated cells to a substrate  
          having magnetic receptacles comprising a localized magnetic  
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field gradient disposed in a two dimensional array thereon so that about 1-5 cells are immobilized on each magnetic receptacle, classified in class 435, subclass 174.

V. Claims 197-214, drawn to a device for arraying about 1-5 cells into a discrete location for further experimentation comprising a substrate having magnetic receptacles comprising a localized magnetic field gradient disposed in a two-dimensional array thereon, classified in class 435, subclass 29.

10 The inventions are distinct, each from the other because:

Inventions I, II, V and III, IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the devices of inventions I, II and V can be used in a materially different method from the methods of inventions III and IV. The devices can be used without trapping or immobilizing about 1-5 cells on each of receptacles as required by the methods of inventions III and IV. The devices of inventions I, II and V can be used for separating cells from a culture medium after using the cells for reacting on a substrate where the cells trapped or immobilized are not arrayed and controlled to about 1-5 cells.

25 The devices of inventions I, II and V are different such that

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each can be made and used without any other. The device of invention I does not require magnetic receptacles comprising a permanent magnet as required by the device of invention II and does not require magnetic receptacles comprising a localized magnetic field gradient 5 disposed in a two-dimensional array as required by the device of invention V. The devices of inventions II and V do not require a cell delivery device, an external magnetic field and a highly-magnetically-permeable material as required by the device of invention I. The device of invention II does hot require two-dimensional array as 10 required by the device of invention V. The device of invention V does not require receptacles arrayed in a discrete pattern as required by the device of invention II.

The inventions of methods III and IV require different steps such that each can be performed without carrying out the other. The 15 invention III method does not require arraying about 1-5 cells at a discrete location for further experimentation, forming a two-dimension array and about 1-5 cells immobilized in each of magnetic receptacles as required by the invention IV method. The invention IV method does not require receptacles disposed in a discrete pattern, washing with a 20 cell-free solution, and the receptacles trapping about 1-5 cells on the substrate as required in the invention III method.

Searching the inventions I-V together will require searching the different features of each invention, and will be a serious search burden.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5       Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance  
10 with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15       The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

20       In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable,  
30 the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See  
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"Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

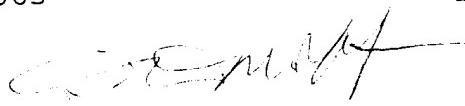
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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David M. Naff  
Primary Examiner  
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DMN

9/15/04